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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,575	07/21/2003	Nils-Gunnar Holmer	150-126	3373

7590

05/05/2006

Steven S. Payne
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EXAMINER

CHENG, JACQUELINE

ART UNIT	PAPER NUMBER
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3768

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/622,575	Applicant(s) HOLMER, NILS-GUNNAR	
	Examiner Jacqueline Cheng	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/20/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Sweden on January 22, 2001. It is noted, however, that applicant has not filed a certified copy of the 0100160-1 application as required by 35 U.S.C. 119(b). Applicant also has not filed a copy of the PCT publication of PCT/SE02/00099.

Information Disclosure Statement

2. The information disclosure statement filed April 20, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Applicant did not provide a copy of foreign patent document JP 10248850. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

3. Claim 17 is objected to because of the following informalities: Claim 17 incorrectly claims dependency on claim 2. Claim 2 has been canceled in a preliminary amendment submitted on July 21, 2003. Examiner has examined the claim as if it were dependent off of claim number 16. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 15-19, 23-27 are rejected under 35 U.S.C. 102(a) as being anticipated by US Patent No. 6,060,943 (herein referred to as Slayton et al).

Claims 15-19, 23-25: Slayton et al. discloses an ultrasonic system useful for imaging, therapy, and temperature monitoring. The ultrasonic imaging sends ultrasonic waves (diagnostic energy) into the body and generates an image, from the echo pulses returned, of the treatment region to assist the user in positioning the transducers to the treatment region. The ultrasonic therapy performs, through an acoustic transducer, therapeutic heating through the skin to the target tissue (abstract). This transducer includes a ceramic plate and other related components that are coupled to the target tissue via a fluid circulating between the acoustic matching layer and an acoustically-transparent membrane. This fluid acts as a coolant for the ceramic plate and the acoustic matching layer and also aids in controlling the temperature of the tissue at the interface. Slayton et al. also discloses temperature control for the circulating fluid, such as a thermoelectric cooling module or any other such device (col. 6 line 52-64). The transducer is controlled by drivers that steer, and/or focus the waves to the region of interest in the target tissue. The heating power and time are also controlled to provide the proper heating pattern and therapeutic dosage (col. 7 line 45-54). The amount of heat generated can be detected by the temperature monitoring subsystem. This subsystem sends out an acoustic pulse wave to a certain boundary such as the

Art Unit: 3768

boundary between tissue and air (the contact surface) (col. 9 line 46) and then reads the temperature from the reflected echoes (col. 8 line 55-col. 9 line 10).

Claim 26 and 27: Slayton et al. discloses that the emitted acoustic waves of the therapeutic ultrasound can be pulsive in the time domain, emitting energy in periods spaced by pauses (col. 5 line 64-col. 6 line 6).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 20 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slayton et al. as applied to claims 15 and 23 above, and further in view of US Patent No. 6,488,626 B1 (herein referred to as Lizzi et al.). Lizzi et al. discloses using an ultrasonic therapeutic system along with a diagnostic ultrasound system to monitor tissue motion. It would be obvious to one skilled in the art at the time of the invention to combine Lizzi et al. with Slayton et al. as the steps of analyzing tissue characteristics and taking diagnostic pulses in between therapeutic pulses can be applied to any type of ultrasonic therapy. Both Lizzi et al. and Slayton et al. claim inventions on the topic of ultrasonic therapy on tissue and diagnosing the tissue.

Claim 20: Lizzi et al. discloses that the analysis of the tissue characteristics is done by comparing the diagnostic ultrasonic echoes taken in the initial tissue condition with the echoes taken immediately after stimulation (col. 5 line 64-col. 6 line 8).

Claim 28: Lizzi et al. discloses a continuous sequence of diagnostic pulses in which therapeutic pulses are pulsed. Following exposure to the therapeutic ultrasound beam, the diagnostic ultrasound echoes are again recorded (col. 4 line 65-col. 5 line 22).

8. **Claims 20 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Slayton et al. as applied to claim 15 above, and further in view of US Patent No. 5,984,881 (herein referred to as Ishibashi et al.). Ishibashi et al. discloses an ultrasound therapeutic apparatus that consists of a therapeutic ultrasonic wave generator and an imaging probe. The imaging probe is used to receive echoes of the ultrasonic pulses. The driving conditions for the therapeutic ultrasonic wave generating source is then adjusted on the basis of the received echo signal (abstract). The system is capable of forcibly stopping the therapy so the system is capable of adjusting the therapeutic waves to stop based on the echo signals of the tissue. It would be obvious to one with ordinary skill in the art at the time of the invention to combine Ishibashi et al. with Slayton et al. as both inventions are in the field of ultrasonic therapy and imaging with temperature monitoring.

9. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Slayton et al. in view of Ishibashi et al. as applied to claim 20 above, and further in view of US Patent No. 6,858,006 B2 (herein referred to as MacCarter et al.). MacCarter et al. discloses a system for monitoring health information of patients. This system includes an ultrasonic sensor that can emit sound waves from the skin's epidermal layer to a distal portion and then calculate the reflection transit time as a correlation to tissue thickness (col. 13 line 5-13). This reflection time

Art Unit: 3768

data is the same as time-of-flight data. It would be obvious to combine MacCarter et al. with Slayton et al. and Ishibashi et al. as Slayton et al. discloses measuring time-of-flight data of the ultrasonic pulses. It would be obvious to one skilled in the art at the time of the invention calculate the tissue thickness from the time-of-flight data which is already taken.

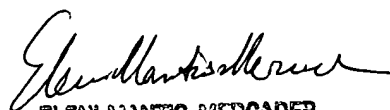
Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JC


ELENI MANTIS-MERCADER
PRIMARY EXAMINER